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February 17, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

RE: FDA (Docket No. 97N-0451)
Microbial Safety of Produce

Dear Sir:

The Food Marketing Institute (FMI) is pleased to have an opportunity to comment on the Food and Drug Administration (FDA) draft document, *Guide To Minimize Microbial Food Safety Hazards For Fresh Fruit and Vegetables* (hereinafter referred to as the *Guide*). FMI's recent experience participating with FDA and others in the development of the *Fight BAC* consumer education campaign serves as an outstanding example of the benefits we all achieve, especially consumers, when we work together for a common goal. FMI, and many others segments of the farm-to-table continuum, are anxious to continue and enhance the partnership that led to the success of our joint education effort.

The Food Marketing Institute (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of \$220 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries.

The retail industry is the direct link to the consumer, and providing the safest food possible is a primary goal of retailers. Consumers expect retailers to provide safe products, and hold them accountable for anything less. That is why the retail industry has a major stake in any initiatives to ensure food safety, and we are in full support of the President's October 2, 1997 memorandum calling for an initiative on fruit and vegetable safety. But consumers in the U.S. also expect an abundant, affordable and quality food supply. According to the Food Marketing Institute's own consumer research, *TRENDS in the United States: Consumer*

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Attitudes and the Supermarket, for over a decade almost all (98%) consumers have ranked high quality fruits and vegetables as a primary reason for choosing a particular supermarket. We cannot jeopardize affordability, availability and quality without proven food safety benefits.

According to FDA officials, the *Guide* is not intended to be regulatory or mandatory, but government recommendations are akin to official advice. One would assume that recommendations from FDA are based on sound scientific data, and are proven, repeatable, and measurable. The Good Agricultural Practices (GAP) described in the *Guide* may be based on common sense, and in some instances may be supportable by science or epidemiology, but there is a lack of documentation in the document to support what real public health benefit will be derived by the specific GAP's recommended. The *Guide* needs to include a risk/benefit analysis or cost/ benefit evaluation to substantiate the basis for the recommendations. Federal regulators should not underestimate the impact of their guidance or recommendations, especially as related to an issue as sensitive and important as food safety. FDA and USDA have an obligation to the public and the industry to assure that complex and costly changes in agriculture practices will have real public health benefits.

FDA and USDA have been leaders in the application of safety programs throughout the food manufacturing system, and this same diligence must be applied to agricultural practices when identifying the hazards that are reasonably likely to result in food borne illness and the controls that can be shown, scientifically, to control such hazards. At a time when FDA and USDA are just embarking on the identification of microbial risk assessment methodologies, it seems far too premature to offer recommendations on addressing the risks that might be present, and changes which may impact on the public health, without the benefit of knowing that such changes will make a difference in the safety of the food we eat.

FMI recommends that FDA and USDA focus their resources on identifying ways to measure the risks associated with various agricultural practices and assess the impact that changes and modifications would have on improving the public health. Using the techniques incorporated in risk assessment, benefit analysis and other reliable, scientific tools would not only enable the government to make realistic, valuable recommendations, but also to position the U.S. internationally as a leader in this area. FDA and USDA should not abandon the approach that has demonstrated a commitment to science, partnerships, and sound food safety changes in lieu of what seems to be a laundry list of ideas from which producers can pick and choose.

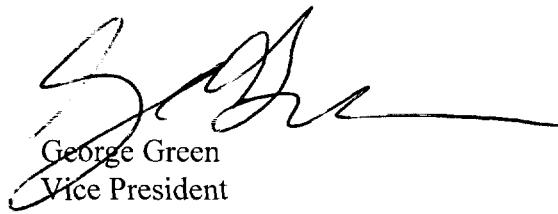
The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has been charged with addressing the issues associated with microbial safety of produce. The public will be better served if FDA and USDA continue to work with industry and

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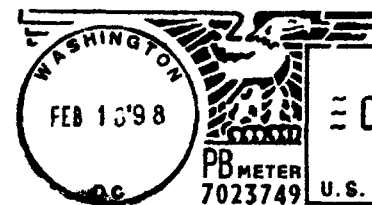
consumers, guided by the Committee, to study and evaluate the factors affecting food safety and the scientifically supportable changes that will reduce foodborne illness. FMI members want to have available the safest foods possible to sell to their customers and will work tirelessly with government to achieve this goal.

Thank you for the opportunity to comment on this draft document. We look forward to working with you in the future on this issue.

Sincerely,



George Green
Vice President
General Counsel



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